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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,711	09/11/2003	Carl R. Merrill	NIH298.IDCICC1	4758
20995 7590 01/07/2008 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER SNYDER, STUART	
			ART UNIT 1648	PAPER NUMBER
			NOTIFICATION DATE 01/07/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/659,711

Applicant(s)

MERRIL ET AL.

Examiner

Stuart W. Snyder

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 20, 22 and 23, as amended in the filing of 6/21/2007, are pending and examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 20, 22 and 23 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The record is clear as to the basis of the Examiner's reasoning concerning enablement of the claims: 1) **The** genetic engineering technique described in the Specification of Applicants' original filing is not sufficient to arrive at the presently claimed invention and 2) there is no convincing evidence that the Specification of Applicants' original filing allows an skilled artisan to produce, by the genetic engineering techniques, a phage "**able to delay inactivation by an animal's host defense system**".

Careful reading of Applicants' original Specification reveals many genetic engineering techniques. There is no description or suggestion that **the** genetic engineering technique would involve the non-inventive reconstruction of a

naturally arising mutation in a phage coat protein, the technique requiring prior knowledge of the nature and location of the mutation. Applicants' arguments in the filing of 11/14/2007 are silent regarding where in the specification such teaching or suggestion is found.

Secondly, claim 22 requires that the phage delay inactivation by the host defense system. Vitiello, et al. provides no such demonstration. Rather than present evidence as to the required mechanism of increased circulation time of viable phage, the authors merely **declare** that they have demonstrated escape from the "innate immune system". An alternate explanation for the observed phenomenon is not ruled out by the data presented: The point mutation may simply provide increased mechanical stability to the phage. In fact, there is no experimental evidence presented regarding the nature of the mechanism of conferring to the phage an increased circulation time and, in fact, no evidence of such experimentation has ever been presented. Declaration is not evidence.

Applicant's arguments filed 11/14/2007 have been fully considered but they are not persuasive. Applicants' arguments regarding enablement are threefold: 1) There is considerable guidance in the specification regarding how to make and how to use the phage, 2) there was high skill in the art, and 3) all of the methods needed to practice the invention were well known. With regard to item number two there is no dispute. With regard to arguments 1) and 3), the Examiner continues to maintain that only prior knowledge of specific point mutations to phage coat proteins that confers the increased circulation phenotype has been shown to

result in the such a phage and that key element is missing from the specification and any art known at the time of filing presented by Applicants for the record.

Rejection of claims 20, 22 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **maintained**.

3. Claims 20, 22 and 23 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of the rejection is a matter of record. Applicants' arguments in the filing of 11/14/2007 do not address the Examiner's reasoning in the mailing of 8/14/2007. Therefore, rejection of claims 20, 22 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **maintained**.

Conclusion

4. No claims are allowed.
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory


action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
Art Unit 1648

SWS


MARY E. MOSHER, PH.D.
PRIMARY EXAMINER